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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,483	10/04/2006	Mitsuru Hasegawa	NPR-192	3141
20374 7590 10/12/2010 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202				
EXAMINER BOSWORTH, KAMI A				
ART UNIT		PAPER NUMBER		
3767				
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10/12/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,483

Applicant(s)

HASEGAWA, MITSURU

Examiner

KAMI A. BOSWORTH

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

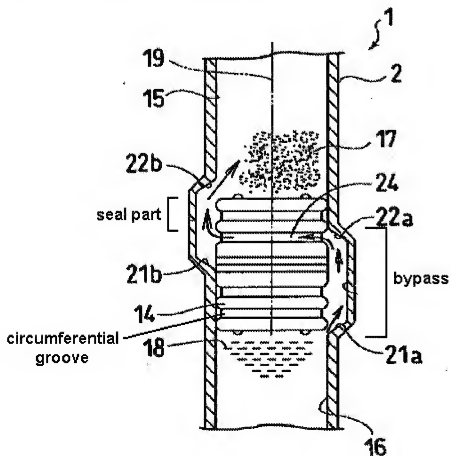
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (PG PUB 2004/0236273) in view of Higashikawa (US Pat 5,830,193).
3. Re claim 1, Tanaka et al. disclose a pre-filled syringe 1 (Fig 1) which comprises a barrel 2 (Fig 1) having a tip 3 (Fig 1) in which a nozzle (the portion of member 6 to which the needle is attached, Para 41) is provided and an open base end 4 (Fig 1) and having an axis 19 (Fig 1) extending from said tip to said open base end, an intermediate gasket 14 (Fig 1,9) liquid-tightly partitioning an inside of the barrel into a front chamber 15 (Fig 1) and a rear chamber 16 (Fig 1) (Para 16,20), a plunger gasket 13 (Fig 1) located in a base end side of the intermediate gasket and sealing the inside of the barrel (Para 20), and a plunger rod 7 (Fig 1) connected to a base end of the plunger gasket (Para 20, Fig 1), and in which in a tip side of the barrel relative to the intermediate gasket there is formed a single bypass 20a (Fig 1,9) protruding outwardly in a radial direction (as seen in Fig 1,9), wherein the intermediate gasket includes a bypass communication passage 24 (Fig 9) providing communication between the front chamber and the rear chamber in cooperation with the bypass (Para 23), the bypass

communication passage consisting of a seal part (portion of gasket toward the tip side of passage 24, as seen in Fig 9 and Fig A below) contacting an inner wall of the barrel and liquid-tightly partitioning the front chamber and the rear chamber (Para 16,20,23), a circumferential groove (between ribs 14, as seen in Fig 9 and Fig A below) formed in an approximately circumferential direction of a base end side of the seal part; wherein an axial length of the intermediate gasket parallel to the axis of the barrel is longer than an axial length of the bypass parallel to the axis of the barrel (as seen in Fig 9), and when the axial length of the bypass is a_1 and an axial effective length of the seal part is b_1 , $a_1 > b_1$ (as seen in Fig 9 and Fig A below); and wherein a powdery medicine 17 (Fig 1,9) is accommodated in the front chamber and a liquid medicine 18 (Fig 1,9) is accommodated in the rear chamber (as seen in Fig 1,9). Tanaka et al. does not disclose a connection passage connecting the circumferential groove and the rear chamber, the connection passage being a spiral groove formed in an outer wall of the intermediate gasket. Higashikawa, however, teaches a gasket 104 (Fig 14) having a circumferential groove 105₁ (Fig 14) formed in an approximately circumferential direction of a base end side of a seal part 109₁ (Fig 14) and a connection passage 108 (Fig 14) connecting the circumferential groove and the rear chamber (Col 10, Lines 8-15), wherein the connection passage is a spiral groove formed in an outer wall of the intermediate gasket (as seen in Fig 14) for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al. to include a connection passage, as taught by

Higashikawa, for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8- 15).

Fig A
(annotated Fig 9 of Tanaka et al.)



4. Re claim 9, Tanaka et al. disclose a tip gasket 12 (Fig 1) but do not disclose that the combined length of three gaskets (tip, intermediate, and plunger gaskets) is greater than the length from a nozzle member to a base end of the bypass. Higashikawa, however, teaches that if an axial length of a tip gasket 26 (Fig 9) parallel to the axis of the barrel is A, an axial length of an intermediate gasket 34 (Fig 9) parallel to the axis of

the barrel is B, an axial length of a plunger gasket 25 (Fig 9) parallel to the axis of the barrel is C and a length from an inner wall tip of a nozzle member 22 (Fig 9) to an inner wall base end of a bypass 24c (Fig 9) is D, $A + B + C > D$ for the purpose of mixing of all components housed in initially separated chambers with one another (Col 8, Lines 33-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al. to include three gaskets whose combined length is greater than the distance between a nozzle member and a base end of a bypass, as taught by Higashikawa, for the purpose of mixing of all components housed in initially separated chambers with one another (Col 8, Lines 33-50).

5. Re claim 10, Tanaka et al. disclose that the barrel additionally comprises a tip gasket 12 (Fig 1), and the front chamber is formed between the tip gasket and the intermediate gasket (as seen in Fig 1; Para 42).

6. Re claim 11, Tanaka et al. disclose that the barrel additionally comprises a nozzle member 6 (Fig 1), the nozzle is formed in a tip of the nozzle member (as seen in Fig 1), and the nozzle member includes a tip gasket accommodation part 10 (Fig 1) capable of accommodating the tip gasket, and a liquid passing passage 11 (Fig 1) through which a liquid medicine can pass when the tip gasket has been accommodated in the tip gasket accommodation part (Para 49).

Response to Arguments

7. Applicant's arguments filed 8/23/2010 have been considered but are moot in view of the new grounds of rejection.

8. Applicant's arguments filed 9/10/2010 have been fully considered but they are not persuasive. Specifically Applicant argues that Tanaka et al. does not disclose "a single bypass" because it contains two bypasses. However, the phrase "...there is formed a single bypass protruding outwardly..." does not exclude multiple bypasses; rather it only requires that the device possess at least one bypass. It appears that the Applicant is attempting to recite that the device only has one bypass; however the language of "a single bypass" does not achieve this desire. Applicant also argues that the intermediate gasket of Tanaka et al. includes at least two seal parts with the bypass communication passage 24 provided between the seal parts. However, bypass communication passage 24 "consists" of the seal part (as noted in Fig A above) because the seal part forms a wall of the passage.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767